

REMARKS

Status of Claims

Claims 1 - 29 were pending in the present application. Claims 17 and 19-23 have been withdrawn from consideration. By virtue of this response, Claims 1-10, 12, and 18 have been canceled, and Claims 11, 13, 16 and 24 have been amended. Claims 30-40 are newly presented herein. Accordingly, claims 11, 13-16, and 24-40 are currently under consideration.

Amendments

Claims 1-10, 12, and 18 have been canceled without prejudice solely to expedite prosecution. Claims 17 and 19-23 have been withdrawn from consideration, in view of the finality of the Requirement for Restriction made by the Examiner in the current Office Action. Applicants reserve the right to file continuation and divisional applications the canceled and/or withdrawn subject matter.

In order to expedite prosecution, the subject matter of the remaining claims has been limited to the elected invention, specifically focusing on compounds of Formula IIa and Formula IIc, each having a substituted pyrimidinyl ring, as recited in pending Claims 11 and 30, as presented herein. Applicants respectfully submit that the pending claims fall within the elected Group I.

Claim 11 has been amended to recite the pyrimidinyl alanine derivative of Formula IIa only and to remove from the claim references to R-groups and the variable, *b*, not referred to in Formula IIa. The compound of Formula IIc, which is also a pyrimidinyl alanine derivative, is now presented in new independent claim 31, along with descriptions of those R-groups present in Formula IIc.

Claims 13 and 16 have both been amended to delete reference to Claim 12, now canceled.

Claim 24 has been amended to depend from Claim 11, instead of Claim 10, now canceled.

Newly presented Claim 30 recites a pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a compound of

Claim 29. Support for this feature of the invention is provided, for example, at page 14, lines 7-9 and page 16, line 25 to page 21, line 37, and by part of original Claim 18, now canceled, which recited a pharmaceutical composition comprising compounds of the invention.

Newly presented Claim 31 recites a compound according to Formula IIc. Support for this feature of the invention can be found, for example, in Claim 11, as originally presented, now amended to recite only compounds of Formula IIa. Likewise, new dependent Claims 32-35 recite the substitution limitations of Claims 13-16, dependent on Claim 11.

Newly presented Claims 36-40 recite pharmaceutical compositions comprising the compounds of Claims 31-35, respectively. Support for this feature of the invention is found, for example, in original Claim 18, which claimed, *inter alia*, pharmaceutical compositions containing the compounds of original Claims 11 and 13-16, as referenced above.

Applicants submit that no new matter has been added by way of the foregoing amendments to the claims.

Rejections under 35 USC §112, second paragraph

a. Claims 1-8, 10, 18 and 24 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for their recital of the limiting phrase “and further wherein the compound of Formula (I) has a binding affinity to VLA-4, as expressed by an IC₅₀ of about 15 μM or less.”

By this amendment, Claims 1-8, 10 and 18 have been canceled, without prejudice, and Claim 24 has been amended so that it is no longer dependent on a claim that recites the phrase objected to by the Examiner. Without acceding to the Examiner's assertions in this regard, applicants submit that the amendments to the claims render this rejection moot.

b. Claims 11, 13-16 and 25-28 were rejected under 35 U.S.C. §112, first paragraph as lacking antecedent basis for a compound having the structure depicted by Formula IIa. By this amendment, Claim 11 is now an independent claim comprising a compound having the structure Formula IIa. Claims 13 and 16 are dependent on Claim 11, Claim 14 is dependent on Claim 13, and Claim 15 is dependent on Claim 14. Claims 25-28 depend on Claims 13-16, respectively. Accordingly, applicants submit that there is proper antecedent basis for the claims as amended.

c. Claims 2-10, 18 and 24 were further rejected as being dependent on Claim 1, and carrying over its limitations. Applicants are unclear as to how this rejection differs from the rejection listed as part "a" under this section; however, since Claims 2-10 and 19 are now canceled, and Claim 24 is now dependent on Claim 11, applicants believe that this rejection has been obviated by the current amendments.

In view of the foregoing, applicants believe that the claims, as currently pending, are in compliance with 35 U.S.C. §112, second paragraph; accordingly, withdrawal of the rejections under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejections under 35 USC § 102(b)

The Examiner rejected Claims 1, 2, 10, 18 and 24 under 35 U.S.C § 102 as allegedly anticipated by Ulane, *et al.* (CA 76:25548s) ("Ulane"); or Ueda *et al.*, (*J. Med Chem.*, 1963 6(6) pg 697) ("Ueda").

Claims 1, 2, 10, and 18 are canceled by this amendment, and Claim 24 has been amended to be dependent on Claim 11. Accordingly, without acceding to the Examiner's opinion with regard to the canceled claims, applicants submit that the rejections under this section are moot. Withdrawal of the rejections under 35 U.S.C § 102 is respectfully requested.

Rejections under 35 USC § 102(e)

The Examiner rejected Claims 1, 2, 10, 18 and 24 as allegedly inherently anticipated by Gonzalez, *et al.* (US 2002/0169101) ("Gonzalez"), a U.S. published patent application filed November 15, 2001 that is a CIP of an earlier U.S. utility patent application filed January 12, 2001, which in turn claims priority to a U. S. utility patent application filed November 9, 2000, which is a 371 filing of an International Application filed May 10, 2000. Since both the International Application and its 371 filing were both filed prior to November 29, 2000, the Gonzalez published application, cannot derive the benefit of either of priority documents for a 102(e) prior art dates. The presumptive 102(e) date for the Gonzalez reference November 15, 2001. While it is noted that the Gonzalez published application is a CIP of a U.S. utility patent application filed January 12, 2001, this parent application would

serve as an effective 102(e) date for this publication only if the parent application contains appropriate subject matter for the Examiner's purposes.

In any case, the applicants' instant application was filed on July 19, 2001 and claims priority to a U.S. provisional application filed on July 21, 2000, which also contains the subject matter rejected by the Examiner under this section. Thus neither the presumptive 102(e) date for the Gonzalez reference (11/15/01) nor its possible parent 102(e) date (1/12/01) can serve as an effective reference against the instant application. Accordingly, applicants respectfully submit that Gonzalez cannot be cited as prior art against the applicants' claimed invention.

The foregoing notwithstanding, the cancellation of Claims 1, 2, 10 and 18, and the amendment of Claim 24 to depend upon Claim 11, obviate any rejection that might occur based on this reference. Withdrawal of the rejections under 35 U.S.C. §102(e) is therefore respectfully requested.

Claim rejections under 35 USC §103(a)

Claims 1, 2, 10, 18 and 24 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Gonzalez, *et al.* (US 2002/0169101) ("Gonzalez").

Applicants respectfully traverse these rejections, for the reasons set forth above, in the section addressing the rejections under 35 U.S.C. §102(e). Accordingly, Gonzalez cannot be cited as prior art against the instant application. That notwithstanding, the cancellation of Claims 1, 2, 10 and 18, and the amendment of Claim 24 to depend upon Claim 11, obviate any rejection that might occur based on this reference. Accordingly withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested.

Claim objections

Applicants note that the Office Action has indicated that the subject matter of Claim 29 is patentable and that the prior art does not teach or suggest these compounds.

The Office Action, however, objects to Claim 29 as being dependent on a rejected base claims. Applicants respectfully submit that this objection is in error. Claims 29, as filed

in the Preliminary Amendment of November 22, 2002, is an independent claim. Withdrawal of this objection is therefore respectfully requested.

CONCLUSIONS


In view of the above amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance. An early and favorable indication to that effect is earnestly solicited. If any matters remain to be resolved, the Examiner is requested to contact the undersigned at 650.856.3700.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2859** referencing docket no. **428372001800**.

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Respectfully submitted,

SWISS LAW GROUP

By 
Carol A. Stratford, Ph.D.
Registration No.: 34,444

Palo Alto, California 94304
(650) 856-3700
Attorneys for Applicant